# Clinical Practice Guideline Development and Antitrust Law

Richard Wolfram

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the greatest focus on care coordination reduced costs and patient hospital stays. It indicated that directing efforts toward most-affected populations and establishing healthy lifestyles early in life may be critical to improving the quality of health and the health care system.

Given the growing burden of chronic disease in the United States, exploration and evaluation of new programs to fight these chronic diseases are important for improving health while reducing the burden of health care costs. Chronically ill patients account for more than 96 cents of every dollar spent in Medicare.[2] Individuals with 2 or more chronic diseases account for 76% of that spending.[3] These are diseases that are largely preventable through maintaining a healthy lifestyle and that, even after diagnosis, can be better managed to maintain quality of life and avoid multiple expensive complications. In the absence of immediate action, failure to optimize health by exploring new ways to prevent and manage chronic disease will cost the United States an estimated $4.1 trillion by 2023.[4] Population-based demonstration programs provide valuable lessons by revealing what works and what still needs refinement to achieve more proactive, evidence-based approaches to reduce health care costs and improve the quality of US health.

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**Additional Information:** Dr Carmona served as Surgeon General of the United States from 2002 to 2006.

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**In Reply:** We agree with Dr Carmona that the most important message from our study is that it may be possible for care coordination programs to reduce hospitalizations and costs, and lessons can be learned from both the successful and the unsuccessful programs. The programs designed their own interventions and decided which chronic illnesses and severity levels to target. A key objective of the demonstration was to identify differences in the interventions and targeting that might explain any observed variation in effects. Our "Comment" section focused on these differences.

Our findings underscore that reducing the need for expensive hospitalizations among people with chronic illnesses is difficult. Successful programs must focus resources on patients at high short-term risk of hospitalizations (eg, within the next year) and should exhibit a number of critical features. Furthermore, success depends not only on incorporating appropriate intervention components but also on implementing them effectively. Many unsuccessful programs appear strikingly similar to successful ones, but closer inspection typically identifies important differences.

We are currently undertaking additional studies to answer 5 key questions: (1) Were programs more successful for patients with higher severity of illness? (2) Were programs more successful after an initial start-up period or after a noteworthy change in their intervention? (3) Did effects vary with the duration of patient enrollment? (4) Did effects vary with physicians' number of patients in the program, and were there spillover effects on control group patients? (5) Did successful programs reduce short-term readmission rates (ie, improve transitional care)? We are investigating how the successful programs implemented key components of their interventions and how that differed from the approach or intensity of the less successful programs.

However, in response to Carmona we must note that our study did not examine population-based interventions. The care management programs in this demonstration differed greatly from commercial disease-management interventions, which have not been successful in Medicare. Only eligible patients who consented to participate were randomly assigned and included in the evaluation. Also, while Carmona is correct that establishing healthy lifestyles early in life is critical, our data shed no light on this issue. However, prevention programs will not eliminate chronic illnesses among Medicare beneficiaries. Such beneficiaries will continue to consume the majority of health care resources. It is likely that their care and their costs can be improved through better patient self-care and adherence, greater physician reliance on evidence-based medicine, better communication among the medical professionals treating the patients and between the patients and medical staff, earlier notification of clinicians of incipient clinical decompensation, stronger transitional care, and increased provision of patient-centered care by the health care system. This and other demonstrations should be used to learn how best to accomplish these ends.

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## Clinical Practice Guideline Development and Antitrust Law

**To the Editor:** The Connecticut attorney general's antitrust investigation and settlement with the Infectious Diseases Society of America (IDSA) regarding its development of clinical practice guidelines for Lyme disease offers important guidance for

strengthening the integrity of clinical practice guideline development and preserving clinical discretion. I believe that in their Commentary, Mr Kraemer and Mr Gostin[1] mischaracterized fact and misread the relevant law in criticizing the attorney general's intervention as political and purporting to defend the supposed positive, scientific character of clinical practice guidelines against the imposition of normative goals. Contrary to their argument, the attorney general's intervention can in fact advance evidence-based medicine.

First, the authors misleadingly likened guideline development—which only faintly resembles the scientific method—to bench science.[2] Guideline development has also proved vulnerable to due-process irregularities, through conduct and conflicts of interest, just as the attorney general found here.

Second, Kraemer and Gostin erroneously asserted that the attorney general found an antitrust violation in the guidelines' recommendation against long-term antibiotics for chronic Lyme disease. The attorney general identified and sought to remedy process and structural abuse[3]—exclusionary conduct and commercial conflicts of interest—and explicitly said he was not "calling" the science. This did not promote normative, political agendas in guideline development; it sought to minimize them.

Third, the authors misapplied the antitrust rule of reason balancing test when they contended that patient benefits outweigh any alleged anticompetitive effects of the Lyme disease guidelines. They assumed the scientific validity of the guidelines, took no account of alleged anticompetitive effects, and ignored the lessons from leading cases. The patient care defense is limited here: "The objective validity of a restraint has never been a defense to an antitrust charge."[4] They miss the point of *Wilk v American Medical Association*: the AMA's concern for patient care did not justify the exclusionary rule at issue, given the existence of a viable, less restrictive alternative—clinical discretion (which complainants also have sought here).

Fourth, the authors incorrectly cited *Schachar* for the proposition that professional guidelines are a "medical not a legal question." This was dictum—extraneous and not precedential. The court found no antitrust violation because it found no restraint of trade. The ophthalmology association's statement was informational only, there was no enforcement or other mandatory intent or effect, and there was no reduction in output (laser surgery). *Schachar* is plainly distinguishable.[5]

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**Financial Disclosure:** Mr Wolfram reported being antitrust counsel to various complainants interested in the Connecticut attorney general's investigation and settlement.

**1.** Kraemer JD, Gostin LO. Science, politics, and values: the politicization of professional practice guidelines. *JAMA*. 2009;301(6):665-667.
**2.** Sniderman AD, Furberg CD. Why guideline-making requires reform. *JAMA*. 2009;301(4):429-431.
**3.** An Agreement Between the Attorney General of the State of Connecticut and the Infectious Diseases Society of America. 3rd prefatory clause. State of Connecticut Web site. http://www.ct.gov/ag/lib/ag/health/idsaagreement.pdf. Accessed April 29, 2009.
**4.** *Indian Head v Allied Tube & Conduit,* 2d Cir (1987), *aff'd*, Sup Crt (1988).
**5.** Wolfram R. Connecticut attorney general investigation and settlement highlights possible applicability of antitrust standard setting law to the development of clinical practice guidelines. *Antitrust Health Care Chronicle*. 2008;22(2):8-16.

**In Reply:** Clinical practice guidelines play a central role in evidence-based medicine. By synthesizing available medical science, they can guide physicians and assist them to ensure that patients receive high-quality care while preventing the costs of treatment that provide uncertain benefit. These guidelines are, of course, only as good as the science that underlies them and the process by which they are created. Recent research shows that, when the science is disputable, practice guidelines often do not give enough attention to valid scientific dispute.[1] But it is only against the best available science that clinical practice guidelines should be measured. The IDSA guidelines appropriately synthesize scientific data on diagnosis, prevention, and treatment of Lyme disease, and the antitrust investigation that resulted from their issuance was justified by neither fact nor law.

Antitrust law is designed to prevent inappropriate restraint of trade. Case law recognizes the ability of professional organizations to create legitimate standards of safety, quality, and practice, and it forbids organizations from using standards to block legitimate competition. For example, in *Wilk v American Medical Association*, a federal court ruled that AMA ethics guidelines violated antitrust law.[2] In the 1970s, the AMA forbade physicians from referring patients to chiropractors.[2] The court noted the AMA's interest in rules that promote patient safety and scientific practice of medicine. However, it ruled that AMA went beyond these legitimate goals in boycotting chiropractic as a whole. The central lesson from this and similar cases is that professional organizations can recommend against particular harmful practices if based in science, but cannot use guidelines as a covert method of harming economic competitors. The IDSA's guidance appropriately reflects scientific evidence and is safely within the former category.

Mr Wolfram suggests clinical discretion as an alternative to the IDSA guidelines. We do not believe that the IDSA guidelines eliminate clinical discretion. Physicians are not bound to the guidelines. However, antitrust law does not require professional organizations to refrain from evaluating scientific evidence and criticizing practices that are not based in evidence.

Attorney General Richard Blumenthal has stressed alleged procedural defects in the IDSA guideline-creation process. Others have noted the problems that can be created when interested parties participate in the guideline-creation process.[3] However, we do not believe that potential conflicts of interest—which were relatively minor and

disclosed—altered the recommendations, which are based in strong scientific evidence. The law in this area turns on whether standard setting is essentially a sham method of suppressing competition as opposed to valid exercise of scientific expertise,[4] and IDSA's process falls within the latter category.

Finally, antitrust law only deals with restraint of trade.[5] Informational guidelines, such as the IDSA's Lyme disease guidelines, are suggestive only. They do not bind clinicians and do not create a restraint of trade. Certainly, the language from *Schacher* that Mr Wolfram quotes, while nonbinding, suggests that courts afford practice guidelines substantial legal deference.

We remain worried that expanded application of antitrust law to clinical practice guidelines will chill medical associations' willingness to issue appropriate guidance on controversial topics.

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**1.** Tricoci P, Allen JM, Kramer JM, Califf RM, Smith SC Jr. Scientific evidence underlying the ACC/AHA clinical practice guidelines. *JAMA*. 2009;301(8):831-841.
**2.** *Wilk v American Medical Association,* 895 F2d 352 (7th Cir 1990).
**3.** Sniderman AD, Furberg CD. Why guideline-making requires reform. *JAMA*. 2009;301(4):429-431.
**4.** *Allied Tube v Indian Head Inc,* 486 US 492 (1988).
**5.** *Schachar v American Academy of Ophthalmology,* 870 F2d 397 (7th Cir 1989).

## RESEARCH LETTER

### Association of Nipple Piercing With Abnormal Milk Production and Breastfeeding

**To the Editor:** Body piercing has become increasingly popular and socially accepted throughout all age groups; it is particularly prevalent in the adolescent population.[1] Current information states that nipple piercing is generally not deemed to be detrimental to maternal milk supply.[2] However, irritation or trauma may predispose a nipple-pierced breast to infant attachment problems or blocked ducts.[3] We present 3 patients with lactation difficulties suggesting that nipple piercings can lead to complications and that these complications can be associated with breastfeeding difficulties.

**Methods**. Patients were lactating women referred to the Human Lactation Research Group at the University of Western Australia for unilateral breast engorgement or poor milk supply. The ethics committee of the University of Western Australia provided approval for this study, and all participants gave informed consent for publication of these data.

Histories were obtained from the patients. All women were given advice regarding positioning and attachment of the infant to the breast. All women also attempted to increase breast-milk supply by expressing after feeds; in particular, mother-infant dyad 1 expressed immediately at secretory activation (lactogenesis II). Expressing was performed to assess whether lack of milk flow was due to nonuse of the breast. In addition, dyads 2 and 3 had been prescribed a galactagogue (domperidone).

Breastfeed volumes were measured by the test weight method.[4] Mammary blood flow was measured by Doppler ultrasound. Breast anatomy and milk ejection were assessed by ultrasound.

**Results**. History, breastfeeding assessment, and management of the mother-infant dyads are presented in the TABLE. All women reported clinical signs of secretory activation in both breasts. However, they reported and we observed that their infants, when fed from the pierced breast, were extremely unsettled compared with feeding from the contralateral breast.

On examination, the nipple piercings were completely healed, with no milk leakage. None of the breasts appeared hypoplastic.

For dyads 1 and 2, minimal milk was expressed or removed by the infant from the pierced breast. There was a marked reduction in blood flow to the pierced breast. Septa were clearly visible with ultrasound in the milk ducts of the pierced breast of dyad 3. Milk ejection was confirmed by visualization of duct dilation. A decrease in the volume of complementary feeds was achieved after postfeed expression and the administration of domperidone in dyads 2 and 3.

**Comment**. These cases indicate that nipple piercing may cause complications leading to duct obstruction so that only negligible amounts of milk can be removed from the breast during lactation. Ineffective milk removal from the breast causes a decrease in milk supply due to local feedback.[5]

These women expressed minimal amounts of milk from their pierced breasts despite frequent breast pumping. The reduction in mammary blood flow is consistent with low milk production because a positive relationship between milk production and blood flow has been shown in animals.[6] Although ductal obstruction is difficult to prove, ductal septa were confirmed in 1 woman. Although a ductogram might have shown ductal patency, the test is limited to 1 ductal system; moreover, catheterization of the nipple duct may be inhibited by scar tissue and carries a risk of infection.

Although the possibility of a spurious association exists, this potential complication should be recognized. Dyad 1 illustrates that with management of lactation, unilateral breastfeeding is possible. Many women have successfully breastfed with a nipple piercing, so it is likely that only a small percentage of women may encounter difficulties during lactation sub-